UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,505	01/15/2004	Caroline Delattre	016800-583	6320

21839 7590 12/23/2004

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,505	DELATTRE ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are presented for examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, drawn to a topically applicable cosmetic/dermatological composition comprising at least one hydrolase polypeptide having amidase activity, or precursor thereof, and at least one modulator of its activity, classified in class 424, subclass 94.63.

II. Claims 22-23, drawn to a regime or regimen for the treatment of dry skin, for combating skin desquamation and/or for promoting cell renewal of the epidermis and/or for promoting skin hydration and/or for promoting cell proliferation and/or differentiation in the skin, classified in class 424, subclass 94.63.

III. Claim 24, drawn to a regime or regimen for the treatment of hyperkeratosis, xerosis, ichtyosis, psoriasis or reactive keratosis, classified in class 424, subclass 94.63.

IV. Claim 25, drawn to a regime or regimen for promoting cicatrization, classified in class 424, subclass 94.63.

V. Claim 26, drawn to a regime or regimen for the treatment of atopic dermatitis, classified in class 435, subclass 195.

VI. Claim 27, drawn to a regime or regimen for promoting desquamation and/or hydration of the skin and/or cell renewal in the skin and/or cell proliferation

and/or differentiation in the skin of an individual in need of such treatment, classified in class 424, subclass 94.63.

VII. Claim 28, drawn to regime or regimen for facilitating the penetration into the skin of a cosmetic/dermatological active agent, classified in class 424, subclass 94.63.

VIII. Claim 29, drawn to a regime or regimen for combating bacterial adhesion to the skin, classified in class 424, subclass 94.63.

IX. Claims 30-31, drawn to a package confining hydrolase polypeptide(s) and modulator(s) of hydrolase polypeptide(s), classified in class 435, subclass 283.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups II-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. The patient populations treated for each group are different because different diseases are being treated which exhibit different symptoms. Treatment of one disease may not render treatment of another disease obvious. Therefore, a search and examination of all these methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive and the subject matter is divergent.

Invention I is related to Inventions II-IV and VI-VIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the hydrolase as described may be used for the commercial production of a desired compound, such as L-ascorbic acid (column 1, lines 63-67 of US Pat. 6,146,860). Furthermore, treatment of the various diseases listed may be accomplished with other products, such as the use of cocoa butter for alleviating dry skin.

The products of Invention I are separate and distinct from the methods of Invention V, wherein the compositions of hydrolase(s) and hydrolase modulator(s) of Invention I may neither be made by nor used in the methods of Invention V, and wherein each does not require the other. Invention I could not be used for Invention V since it consists of hydrolase, which is not required for Invention V. Likewise, the products of Invention IX are separate and distinct from the methods of Inventions II-VIII, wherein the packages of Invention I may neither be made by nor used in the methods of Inventions II-VIII. Accordingly, restriction is proper.

Inventions I and IX are drawn to patentably distinct products, wherein each has a different structure and function which require separate searches, and wherein each is capable of separate manufacture and use. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are products which have materially different ingredients. The compositions of Invention I may be used for treatment of diseases and product formation, while the packages of

Invention IX may be used to contain a variety of products not limited to hydrolases and hydrolase modulators.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

(a) the additional ingredients recited in claim 17 (beta-hydroxy acid; alpha-hydroxy acid; alpha or beta-keto acid; urea; gentisic acid; oligofucoses; cinnamic acid; Saphora japonica extract; resveratrol or derivative thereof; glycosidase, *stratum corneum* chymotryptic enzyme or other serine or cysteine protease; chelating agent; aminosulphonic compound; sugar derivative; reducing agent and/or retinoid); and

(b) the diseases listed in claim 24 (hyperkeratosis, xerosis, ichtyosis, psoriasis, reactive keratosis).

If applicant elects group I, as set forth above, applicant is required under 35 U.S.C. 121 to elect a **single** disclosed species of (a) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If applicant elects group III, as set forth above, applicant is required under 35 U.S.C. 121 to elect a **single** disclosed species of (b) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Thus, a properly responsive election would appear as follows: --

Applicant hereby elects, with traverse, group III, claim 24, drawn to a regime or regimen for the treatment of hyperkeratosis, xerosis, ichtyosis, psoriasis or reactive keratosis. Applicant also elects, with traverse, hyperkeratosis as the disease to be treated by the regime or regimen.

--.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35U.S.C.

§§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to maintain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the protection against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan E. Fernandez
Assistant Examiner
Art Unit 1651

sef

FRANCISCO PRATS
PRIMARY EXAMINER